SECTION 17

PRETREATMENT STANDARDS FOR EXISTING SOURCES (PSES) AND PRETREATMENT STANDARDS FOR NEW SOURCES (PSNS)

17.1 Introduction

Pretreatment standards for existing sources are designed to prevent the discharge of pollutants which pass through, interfere with, or are otherwise incompatible with the operation of POTWs. The CWA requires pretreatment for pollutants that pass through POTWs in amounts that would exceed direct discharge effluent limitations or limit POTW sludge management alternatives, including the beneficial use of sludges on agricultural lands. EPA also determines that there is pass through of a pollutant if the pollutant exhibits significant volatilization prior to treatment by POTWs. Pretreatment standards are to be technology-based and analogous to the BAT for removal of priority and nonconventional pollutants.

Section 307(c) of the CWA requires EPA to promulgate pretreatment standards for new sources at the same time that it promulgates NSPS. New indirect discharging facilities, like new direct discharging facilities, have the opportunity to incorporate the best available demonstrated technologies, including process changes and in-plant treatment technologies that reduce pollution to the maximum extent feasible. Pretreatment standards for new sources (see Section 16 for a discussion of the definition of new source) are to be technology-based and analogous to the NSPS for the removal of priority and nonconventional pollutants.

The owners or operators of facilities subject to PSES or PSNS are not required to use the specific process technologies and wastewater treatment technologies selected by EPA to establish the PSES or PSNS, but may choose to use any combination of process technologies and wastewater treatments to comply with permit limitations derived from the PSES or PSNS.

The Agency has selected in-plant steam stripping for organics and ammonia as the technology basis for the PSES for Subcategory A and C operations. The Agency has selected in-plant steam stripping for organics as the technology basis for the PSES for Subcategory B and D operations.

The Agency has selected in-plant steam stripping for organics and ammonia as the technology basis for PSNS for Subcategory A and C operations. The Agency also selected in-plant steam stripping for organics as the PSNS for Subcategory B and D operations. The rationale behind these selections is discussed in Section 11.

The Agency is making changes to the current PSES/PSNS effluent limitations set for cyanide in the October 27, 1983 regulation for the pharmaceutical manufacturing industry. Specifically, EPA is withdrawing the PSES/PSNS regulation for cyanide at Subcategory B and D facilities. EPA is retaining the existing PSES/PSNS regulations for cyanide at Subcategory A and C facilities. In addition, the Agency is clarifying that the existing in-plant cyanide limitations apply to Subcategory A and C facilities unless a facility can demonstrate compliance with the existing end-of-pipe cyanide limitations and standards with a measurable amount of cyanide in the facility's effluent. A facility effluent cyanide concentration of "not detect" is more likely to represent dilution instead of treatment and therefore, in these cases, the limitations and standards should be applied in-plant at the point of cyanide destruction.

The following information is presented in this section:

- Section 17.2 reviews the subcategories regulated by PSES and PSNS, the results of the Agency's POTW pass-through analysis to determine pollutants regulated by PSES and PSNS, and presents the selected PSES and PSNS; and
- Section 17.3 discusses PSES and PSNS implementation with regard to point of application, permit limitations, and monitoring and compliance issues.

17.2 Summary of PSES and PSNS

17.2.1 Regulated Subcategories

PSES and PSNS have been revised for Subcategories A, B, C, and D. As discussed in Section 4.3, Subcategories A, B, and C include wastewater discharges resulting from the manufacture of

pharmaceuticals by fermentation, biological or natural extraction processes, and chemical synthesis processes, respectively. Subcategory D includes discharges resulting from mixing, compounding, and formulating of pharmaceutical products.

17.2.2 POTW Pass-Through Analysis

The Agency has evaluated POTW pass through for those pollutants selected for regulation as listed in Section 6.6 and 6.7. In determining whether a pollutant is expected to pass through a POTW, the Agency assessed the following:

- Whether the pollutant would be volatilized from conveyance systems, equalization or other treatment units or POTW head works which are open to the atmosphere;
- Whether the nation-wide average percentage of a pollutant removed by well-operated POTWs achieving secondary treatment is less than the percentage removed by the BAT model treatment system; or
- Whether there are any specific instances of POTW interference, upset, or pass through known to the Agency as being caused by the pollutants selected for regulation.

For promulgation, EPA used an inclusive approach to determine pass through instead of a divided multi-pronged approach when considering pass through criteria. At proposal and for the NOA, EPA considered whether a pollutant would readily volatilize to the air prior to treatment or whether a pollutant would pass through based on the BAT/POTW pollutant percent removal comparison. If a pollutant met the pass-through criteria for either of these criteria, the pollutant was considered to pass through. For promulgation, EPA adopted a more unified approach where a pollutant needed to meet the pass through criteria based on pollutant volatility, solubility, and the BAT/POTW pollutant percent removal comparison in order to be considered to pass through. The approach was developed in consideration of the unique characteristics of pharmaceutical industry wastewater, and the attributes of the selected BAT and PSES technology bases. Lastly, pollutants known to cause treatment problems at POTWs accepting pharmaceutical manufacturing wastewaters were considered for regulation.

Presented below are brief descriptions of PSES pass-through analysis methodologies utilized for proposal and the NOA as well as a more detailed discussion of the methodology and results of the adopted PSES pass-through analysis used for the final regulation.

17.2.2.1 May 2, 1995 Approach

In the May 2, 1995 proposal, the Agency used a two-pronged approach for identifying pollutants that potentially pass through POTWs. This approach consisted of the volatility override and POTW percent removal in comparison with the BAT percent removal. Both criteria were carried through for the final POTW pass-through analysis, with some modifications to the data editing.

Pollutant Volatility Analysis

POTW pass-through was assumed to occur for those compounds with significant volatilization in the collection systems and head works of POTWs, thereby reducing the amount of organics that can be biodegraded in the POTW secondary treatment works. In evaluating a pollutant's volatility, EPA looked at the pollutant's Henry's Law Constant, the emissions predicted for that pollutant by WATER7 modeling for direct dischargers (1), and whether the pollutant was identified as a wastewater pollutant requiring control in the Hazardous Organic NESHAP (HON) (59 FR 19402, 4/22/94) (2).

Based on the analysis of Henry's Law Constants, the estimate of pollutant air emissions from the WATER7 fate analysis at direct dischargers and the inclusion of pollutants in the HON wastewater provisions, those pollutants with a Henry's Law Constant equal to or greater than that of methanol (1.0 x 10-6 atm/gmole/m3) were identified as being volatile. These pollutants were determined to potentially be volatilized to the air before reaching treatment at POTWs and were therefore considered to pass through.

BAT and POTW Percent Removal Analysis

The traditional pass-through analysis evaluates the percentage removal of a pollutant in POTWs nationwide with the proposed BAT percent removal for the same pollutant. In evaluating the POTW percent removal nationwide, EPA primarily used the Domestic Sewage Study Report (3) as well as other sources of bench- and pilot-scale biological treatment performance data. The Agency used pollutant loading information provided by the industry in their 1990 detailed questionnaire responses and the long-term mean treatment performance concentrations developed for each pollutant after application of the BAT treatment technology(ies) in developing BAT percent removal values.

POTW pollutant percent removals were determined either from specific sources or by transfer of a POTW percent removal from a similar constituent when data were not available. POTW percent removal data were collected from the following sources: The Domestic Sewage Study (DSS), sampling episode report for the Syracuse POTW, and the US EPA Risk Reduction Engineering Laboratory (RREL) Treatability Database (4). BAT pollutant percent removals were determined using the raw loadings data (represented as the sum of the pollutant load from air emissions from wastewater prior to discharge, discharges to surface water, or degraded/destroyed on-site) and the effluent loadings data (calculated from the proposed BAT long-term mean treatment performance concentrations, facility wastewater flow, and appropriate conversion factors) that would be achieved if BAT were in place at these facilities. A percent removal was then determined between the raw and effluent loads for each candidate pollutant. A load weighted average percent removal was calculated to represent nationwide BAT percent removal where multiple direct discharging facilities were discharging the same pollutant of concern.

Evidence of Pass-Through

In February 1993, EPA sent a survey to nine POTWs known to receive pharmaceutical manufacturing industry discharges. These responses were reviewed to identify pharmaceutical candidate pollutants from pharmaceutical plants that may be causing upsets or pass-through at POTWs. In addition, data collected by EPA from the Syracuse POTW and data submitted

previously to EPA by the Syracuse POTW were also reviewed for evidence of pollutants that may cause POTW upset or pass through. Based on these reviews, POTW personnel have reported POTW interference or upset by discharges from pharmaceutical facilities of ammonia, tetrahydrofuran, and dimethyl sulfoxide (5).

17.2.2.2 August 8, 1997 NOA Approach

EPA used the same basic approach for determining pollutant POTW pass-through for the NOA as at proposal. EPA considered pollutant volatility, BAT pollutant percent removal compared to POTW pollutant percent removal, and potential POTW upsets. The following paragraphs note the revisions made to the original POTW pass-through analysis upon receiving public comments to the proposal and additional data.

Pollutant Volatility

EPA considered three options for the volatile override approach for the NOA. The first option was to have the override cutoff at a Henry's Law Constant of 1.0×10-5 atm/gmole/m3 based on the precedent in the OCPSF rulemaking (52 FR 42522). The second option was to have an override cutoff based on a Henry's Law Constant of 1.0×10-4 atm/gmole/m3. The last option was to eliminate the volatility override approach. The three options were considered in response to commenters who opposed the proposed cutoff claiming it was too low.

Percent Removal Analysis

EPA made modifications to its BAT pollutant percent removal and POTW pollutant percent removal analyses based on comments from the industry and acquired new data.

BAT Percent Removal

The following modifications were made to the proposal BAT pollutant percent removal calculations:

1. Facility data sets that had an influent load less than ten times the proposed option load were removed from consideration;

2. BAT percent removal was calculated for each facility pollutant combination, and the median percent removal for each pollutant was used to compare with the POTW percent removal; and

3. Three different options, each considered as the basis for BAT were used to determine POTW pass-through. The first option included steam stripping followed by advanced biological treatment; the second, biological treatment; and the third, based on EPA's OAQPS percent removal of partially soluble/ soluble pollutants assuming 99% and 90% removal, respectively.

POTW Percent Removal

The following modifications were made to the POTW pollutant percent removal calculations:

1. Unacclimated DSS data were discarded from further evaluation and acclimated DSS data were used;

2. Data sets were edited so that influent concentrations less than ten times the detection limit were discarded from further evaluation (this did not apply to the acclimated DSS data because raw data from the DSS are not available);

3. DSS data were compared with other POTW sources and EPA determined that the data showed no significant differences between the percent removals achieved by the DSS POTWs and the POTWs submitting their own data. Therefore, the DSS percent removals were considered reliable;

4. The nationwide POTW pollutant percent removal was calculated as the median of all acclimated POTW data submitted; and

5. The data transfers made from secondary alcohols to primary alcohols were evaluated. Transfers to primary alcohols were revised such that the transfers were made from a primary alcohol.

Comparison of BAT and POTW Percent Removals

EPA considered differential ranges between BAT pollutant percent removal and POTW pollutant percent removal, assuming that once the percent removals were within a certain range of each other, they were essentially equivalent. Differential ranges of 2% and 5% were considered equivalent to a no pass-through determination. That is, if the POTW removal percentage was within 2 or 5 percent of the BAT removal percentage for a pollutant, the pollutant would be determined not to pass through.

17.2.2.3 Adopted Approach

After reviewing the public comments received on the August 8, 1997 NOA pass-through methodology evaluation, the Agency again examined its methodology and instituted a final set of changes. The Agency modified its two-pronged approach to a more inclusive approach and several criteria were met before a pollutant was determined to pass through a POTW. These criteria included: a volatility analysis, an evaluation of solubility in water, and a BAT and POTW pollutant percent removal comparison. Again, this approach was developed in consideration of the unique characteristics of pharmaceutical industry wastewater.

Volatility Analysis

Consistent with the OCPSF, Pesticides, and Central Waste Treaters (CWT) rule, EPA considered pollutants with a Henry's Law Constant greater than 1.0x10-5 atm/gmole/m3 to significantly volatilize to the air before reaching treatment at a POTW. This cutoff level is greater than the cutoff level presented at proposal and addresses commenters concerns that the proposal cutoff level was too low. The list of organic pollutants that EPA has determined pass through POTWs based on this criterion are shown in Table 17-1.

BAT and POTW Percent Removal Comparison

The Agency evaluated the percentage removed by the BAT model treatment systems using the detailed questionnaire data submitted by direct dischargers and the long-term mean treatment performance concentrations developed for the BAT treatment technology as discussed in Section 8. At the time of the NOA, data pairs with raw influent loads less than ten times the proposed option load were removed from the analysis. For promulgation, EPA modified this approach so that all pollutant data sets were edited to remove data pairs with raw influent concentrations less than ten times the pollutant detection limit. The adopted approach better indicates whether pollutants are present in raw wastewater at treatable levels. The approach used at the NOA for determining median BAT pollutant percent removal was also adopted for the final rule.

The sources of the average percentage of a pollutant removed by well-operated POTWs achieving secondary treatment included the acclimated percent removals reported in the Domestic Sewage Study, data from the 40 Plant Study, the USEPA Risk Reduction Engineering Laboratory Treatability Database (RREL), and various reports of POTW performance submitted to EPA prior to and after the May 2, 1995 proposal. The data editing criteria used at the NOA for editing POTW percent removals were not modified for the final rule. The list of organic pollutants that EPA has determined pass-through POTWs based on this criterion are also shown in Table 17-1.

The Agency decided not to use a 2 or 5 percent differential and concluded that the most reasonable approach is to accept the available data as the best information on the relative percent removals of BAT and POTWs and to perform a BAT/POTW comparison directly based on that data. EPA decided that such an approach was unbiased in that it does not favor either the over-statement or under-statement of pass-through for the pollutants.

Water Soluble Compounds

The Agency used several sources to evaluate the fate of alcohols and related compounds in pharmaceutical manufacturing wastewater treatment systems. For the purpose of this analysis,

water soluble compounds are alcohols or related compounds that are biodegradable and are no more strippable than amyl alcohol (based on a Henry's Law Constant cutoff of 2.23×10^{-5} atm/gmole/m^3). EPA adopted this approach in order to be consistent with the MACT standards which state that water soluble compounds are less likely to volatilize than compounds that are partially soluble. The following data sources were used in this analysis:

- EPA and Pharmaceutical Research and Manufacturers Association (PhRMA) wastewater samples collected from the primary treatment works at the Barceloneta POTW in Barceloneta, Puerto Rico;
- WATER8 air emissions modeling of the Barceloneta POTW;
- An industry submitted literature study evaluating volatilization potential in sewers; and
- An industry submitted study evaluating volatilization potential in an enclosed equalization tank.

EPA and PhRMA conducted sampling at the Barceloneta POTW to obtain data on the removal of alcohols (methanol, ethanol, and isopropanol) and other oxygenates in the primary treatment works of a POTW. The Barceloneta POTW was selected for sampling because the influent wastewater to this POTW was known to contain measurable quantities of alcohols and other pollutants for which pretreatment standards were proposed in May 1995. Three separate sampling episodes were conducted at this POTW. They consisted of:

- In August 1996, EPA and PhRMA collected wastewater samples from the influent to the treatment system, the effluent from the aerated grit chamber, and the effluent from the primary clarifier. EPA's lab analyzed the results using analytical Method 1671, whereas PhRMA's lab analyzed the results using Method 8015. EPA performed a biodegradation study to determine the extent to which pollutants were aerobically biodegraded in the aerated grit chambers.
- In April 1997, PhRMA conducted an anaerobic (anoxic) biodegradation study on the primary clarifier influent using Methods 1671 and 8015. EPA used the data obtained from Method 1671 to determine the overall biodegradation and volatilization rates associated with the August 1996 data.

- In August 1997, PhRMA conducted additional sampling around the primary clarifier to determine if more frequent sampling would explain all or part of the alcohol losses measured in the August 1996 study.

Samples were collected in the influent and effluent from treatment units. Percent loss across the treatment units was calculated from the influent and effluent mass from the unit. Percent losses were assumed to be due to two major fate pathways: biodegradation and volatilization. Knowing the overall percentage loss and the loss estimated to be attributed to biodegradation (both aerobic and anoxic), EPA estimated the percent of loss attributed to volatilization. The sampling results shown in Table 17-2 indicate the range of percent loss of alcohols in the primary treatment units due to volatilization.

In addition, EPA performed WATER8 air emissions modeling of the Barceloneta POTW using the sampled pollutant influent concentrations in order to obtain an estimate of how much volatilization of volatile organic pollutants occurs throughout the entire POTW system (6). The results of the modeling study shown in Table 17-3 show less volatilization in the primary treatment portion than the measured data from the Barceloneta POTWs sampling episode suggests.

EPA also evaluated an industry submitted study evaluating sewer losses for water soluble compounds. The results of this study indicate that volatilization of methanol and ethanol in closed sewers is expected to be minimal with maximum emission rates of 0.03 and 0.19% being projected under most sewer conditions, respectively. However, under open sewer conditions, volatilization percentages of methanol and ethanol could be as high as 6.5 and 20%, respectively (7).

Since the August 8, 1997 NOA, EPA also has received information on a study conducted by Pfizer at its Groton, CT production facility to analyze the volatilization of methanol from their enclosed equalization tank (primary treatment at their biological treatment system). The equalization tank is covered and vented to a combustion device and is mixed with a jet aeration system. The headspace of the tank is under negative pressure due to an induced airflow by an auxiliary combustion blower downstream of the tank vent. The study included air samples to

determine the concentration of the selected organics in the head space of the equalization tank and influent and effluent wastewater samples.

The results of the above study show an average methanol concentration of 500 mg/L in the equalization tank and an average vent gas methanol concentration of 70 ppmv. This results in a volatilization loss of methanol of 0.31% (assuming that the only loss of methanol in the tank is volatilization).

POTW Pass-Through Determination

Based on EPA's review of the total body of measurement and modeling data, data from other POTWs, a facility submitted equalization study, literature articles submitted by commenters, and facility submitted data for on-site wastewater treatment systems related to the volatilization of water soluble organics in pharmaceutical manufacturing industry wastewater, EPA has concluded that these pollutants will not volatilize to a significant extent to the air prior to treatment and are biodegraded in POTWs. Although these data sources yield conflicting information as to the extent of volatilization and biodegradation in primary and secondary treatment, most results show at least 90% treatment (biodegradation) of alcohols (not including volatilization). This percentage is in accordance with the 90% treatment required by the MACT for soluble HAPs and is equivalent to the losses likely occurring at direct discharger biological treatment systems. Therefore, EPA concludes that alcohols and related compounds will not pass through. The list of organic pollutants that EPA has determined pass-through POTWs based on this criterion are also shown in Table 17-1.

Organic pollutants that meet the pass-through criteria based on volatility, the BAT/POTW percent removal comparison, and solubility in water were selected for regulation for indirect dischargers.

Of the three pollutants (dimethyl sulfoxide, tetrahydrofuran, and ammonia) identified as problem pollutants from the 1993 POTW survey, dimethyl sulfoxide is a pollutant that is not treated by steam stripping, the technology basis for PSES and PSNS, and EPA has not promulgated pretreatment standards for this pollutant. Tetrahydrofuran is found to pass through POTWs since

it meets the before mentioned pass-through criteria. Ammonia is considered to pass through because many POTWs do not have nitrification capability that is part of the BAT model treatment system and therefore they will not achieve as much ammonia removal as the BAT model treatment system. However, EPA concluded that ammonia does not pass through for indirect discharging facilities that discharge to POTWs with nitrification capabilities based on an evaluation of EPA and POTW nitrification data. Thus, PSES ammonia limitations will not apply to Subcategory A and C facilities discharging to POTWs with well-operated nitrification systems. POTWs with nitrification capability are defined as being able to oxidize ammonium salts to nitrites (via nitrosamas bacteria) and then further oxidize nitrites to nitrates (via nitribacter bacteria) and achieve greater removals of ammonia than POTWs without nitrification. Nitrification can be accomplished in either a singe or two-stage activated sludge system. Indicators of nitrification capability are 1) biological monitoring for ammonia oxidizing bacteria (AOB) and nitrite oxidizing bacteria (NOB) to determine if nitrification is occurring, and 2) analysis of the nitrogen balance to determine if nitrifying bacteria reduce the amount of ammonia and increase the amount of nitrite and nitrate.

EPA did receive and review data to determine whether COD should be considered to pass through POTWs. EPA has determined based on its data that COD does not pass through POTWs and is not regulating COD under PSES or PSNS. With regard to the priority pollutant cyanide, EPA found that this pollutant passes through POTWs because the removal of cyanide by the BAT cyanide destruction systems is significantly greater than the documented removals by well-operated POTWs achieving secondary treatment. For a detailed discussion of the Agency's POTW pass-through analysis see the memorandum entitled, "Final POTW Pass-Through Analysis for the Pharmaceutical Manufacturing Industry" (8) which is located in the Record for this rulemaking.

17.2.3 Regulated Pollutants

Section 6.0 of this document discusses potential pollutants to regulate for the pharmaceutical manufacturing industry. The set of potential pollutants to regulate for Subcategory A and C

dischargers is different from the set of potential pollutants to regulate for Subcategory B and D dischargers. EPA separately applied the pass-through criteria to both sets to determine the final list of regulated pollutants for each respective subcategory. EPA is regulating 24 priority and nonconventional pollutants (including ammonia, where applicable, and cyanide) for indirect dischargers in Subcategories A and C. EPA is regulating 5 priority and nonconventional pollutants for indirect dischargers in Subcategories B and D.

The final PSES and PSNS establish effluent standards for the priority and nonconventional pollutants listed in Table 17-4 for indirect discharges in Subcategories A, B, C, and D.

17.2.4 PSES and PSNS

The effluent limitations for PSES and PSNS for each subcategory are based on a combination of long-term mean treatment performance concentrations and variability factors that account for day-to-day variation in measured treated effluent concentrations. Long-term mean treatment performance concentrations, discussed in Section 8, are target values that a facility should achieve on a long-term, average basis. The variability factors, discussed in the Statistical Support Document (9), which is located in the Record for this rulemaking, represent the ratio of an elevated value that would be expected to occur only rarely to the long-term mean. The purpose of the variability factor is to allow for variations in effluent concentrations that comprise the long-term mean. A facility that designs and operates its treatment system to achieve a long term mean on a consistent basis should be able to comply with the daily and monthly limitations in the course of normal operations.

The PSES are the same for Subcategories A and C, and then the same for Subcategories B and D. The same is true for PSNS. The PSES and PSNS for Subcategories A and C are presented in Table 17-5. The PSES and PSNS for Subcategories B and D are presented in Table 17-6. These standards were determined by multiplying the long-term mean treatment performance concentrations for the selected treatment technology bases by the respective 1-day and 4-day variability factors (VFs).

The PSES/PSNS for diethylamine, methyl cellosolve, and triethylamine are based on the analytical method minimum level. The minimum level for a pollutant is the level at which an analytical system gives recognizable signals and an acceptable calibration point. For pollutants with a long-term mean below the minimum level, typically in cases where treatment performance was established through data transfer, the final long-term mean was set at a value no lower than the minimum level for the pollutant. The final pretreatment standards are determined by applying 1-day and 4-day variability factors to the final long-term means.

The PSES/PSNS cyanide effluent standard, established in the 1983 Final Rule to be a daily maximum of 33.5 mg/L and a maximum monthly average of 9.4 mg/L for all subcategories, is not being revised for Subcategories A and C. The cyanide limit is being withdrawn for Subcategories B and D because EPA has determined that cyanide is neither used nor generated by facilities with these subcategory operations.

The PSES/PSNS ammonia standard for Subcategory A and C operations that discharge to non-nitrifying POTWs is being set equal to the corresponding BAT ammonia effluent limit. EPA has decided to set the PSES/PSNS ammonia standard at a level higher than the standards based on steam stripping treatment performance data in response to commenters who want to be able to comply with the ammonia standards at indirect dischargers using biological treatment with nitrification technology.

17.3 Implementation of the PSES and PSNS

The PSES and PSNS standards for Subcategory A and C and Subcategory B and D operations are presented in Tables 17-5 and 17-6, respectively.

17.3.1 Establishing List of Pollutants for Compliance Monitoring

Permitting authorities should establish permit limitations and compliance monitoring requirements for each regulated pollutant listed in Table 17-4, generated or used at a pharmaceutical manufacturing facility. Limitations and routine compliance monitoring should not be required for

regulated pollutants not generated or used at a facility. A determination that regulated pollutants are not generated or used should be based on a review of all raw materials used and an assessment of all chemical processes used, considering resulting products and by-products. The determination that a regulated pollutant is not generated or used would need to be confirmed by annual chemical analyses of wastewater from each monitoring location. Such confirmation would be provided by an analytical measurement of a non-detect value.

Facilities discharging more than one regulated organic pollutant may monitor for a single surrogate pollutant to demonstrate an appropriate degree of control for a specified group of pollutants. For the purpose of identifying surrogates, pollutants are grouped according to treatability classes; Table 17-7 presents the treatability classes identified for steam stripping, which is the PSES/PSNS technology basis for organic pollutant limitations. For treatability classes with more than one possible surrogate pollutant, the analyte with the highest concentration or loadings should be chosen as the surrogate pollutant. Plants may monitor for a surrogate pollutant(s) only if they demonstrate that all other pollutants receive the same degree of treatment.

An individual plant may choose to demonstrate by selecting a monitoring pollutant for a given treatability class and maintaining documentation, including flow information and sampling results, that all pollutants in that treatability class receive equivalent treatment. The documentation is then submitted to the permit authority for approval.

17.3.2 Point of Application

The PSES and PSNS standards for wastewaters from Subcategory A, B, C, and D operations are applicable at an end-of-pipe discharge point for all pollutants (except cyanide), as denoted in Tables 17-5 and 17-6. The end-of-pipe monitoring point should be placed prior to discharge to the POTW sewer system. Cyanide should be monitored in-plant for Subcategory A and C wastewaters unless a facility can show a measurable amount of cyanide at end-of-pipe, instead of a non-detect in accordance with 40 CFR 403.6 (e)(2) and 403.6 (e)(4).

17.3.3 Permit Limitations

End-of-pipe permit limitations based on the PSES and PSNS limitations for ammonia (for Subcategories A and C) and organic constituents will be mass-based. To determine PSES and PSNS limits, permit writers should use a reasonable estimate of process wastewater discharge flow and the concentration-based standards listed in Tables 17-5 and 17-6 to develop mass-based permit limitations. Section 15.3.3 presents guidance regarding how a reasonable estimate of process wastewater discharge flow would be established after final PSES and PSNS are adopted.

EPA expects that permit limitations for cyanide, based on the 1983 PSES limitations, at in-plant locations will be concentration-based, and not converted to a mass basis. A concentration basis should be used for cyanide because it offers a direct benchmark to assess whether the in-plant control technology is achieving the intended PSES and PSNS levels. In-plant wastestreams that require control may be generated or treated on a variable, batch basis. In such a setting, mass-based permit limitations are difficult to establish accurately, and compliance is hindered because the permitted facility cannot make a direct measurement to determine if its control technology is performing at the required level. Concentration-based permit limitations eliminate these problems and offer a direct measure of cyanide to both the permitting authority and the permitted facility that PSES and PSNS performance levels are being achieved.

17.3.4 Monitoring and Compliance

The compliance monitoring frequency for ammonia and all other regulated organic constituents should be performed on a frequency basis established by a permit writer or pretreatment authority. EPA's monitoring costs for this regulation assumed compliance monitoring for ammonia (for Subcategory A and C facilities) and all regulated organic constituents on a weekly basis for Subcategory A, B, C, and D facilities. The list of pollutants for which monitoring will need to be performed includes all constituents from Subcategory A, B, C, and D operations listed in Table 17-4 generated or used in pharmaceutical manufacturing processes at the facility unless the facility discharges ammonia to a POTW with nitrification capabilities in which case an ammonia no pass-through determination may apply. Monitoring of regulated constituents generated or used in any

pharmaceutical manufacturing processes at the facility would occur at every process wastewater end-of-pipe discharge point for compliance with PSES and PSNS effluent standards.

Compliance with mass-based permit limitations is determined by multiplying the measured concentrations of a regulated pollutant in the effluent sample by a conversion factor and the total wastewater flow at the monitoring point during the effluent sampling period. Thus, the mass compliance value should be based on the total flow discharged on the day of sampling, not on the long-term average flow rate that provided the basis for establishing the permit limitations.

Compliance monitoring for cyanide should occur in-plant, prior to commingling or dilution with non-cyanide-bearing wastewater, unless a facility can show end-of-pipe monitoring for cyanide is feasible. To show that end-of-pipe monitoring is feasible, the facility would need to demonstrate compliance with cyanide limitations, adjusted as necessary to account for dilution with non-cyanide-bearing wastewater, at a level above the detection limit for cyanide.

The list of pollutants for which monitoring would be required should be updated based on consideration of raw material and process changes throughout the facility and an annual scan for all regulated pollutants listed in Table 17-4. The annual scan should be performed at the compliance monitoring point(s) to identify any regulated pollutants in the wastewater. Permit monitoring and compliance should be required at all monitoring locations for all pollutants detected at any locations.

Dischargers must use the test methods promulgated at 40 CFR Part 136.3 or incorporated by reference in the tables of that Part, when available, to monitor pollutant discharges from the pharmaceutical manufacturing industry, unless specified otherwise in Part 439 (See 40 CFR 401.13) or by the permitting authority.

As a part of the final rule, EPA promulgated additional test methods for the pollutants to be regulated under Part 439 for which there are no test methods listed at 40 CFR Part 136.3. To support the Part 439 regulations at the time of proposal, EPA published test methods developed

specifically for the pharmaceutical industry in a compendium entitled, "Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater," EPA-821-B-94-001. These test methods were discussed in the proposed rule and have been revised in response to public comment. The revised test methods are available for monitoring some pollutants covered by the final rule. The revised test methods are available for monitoring some pollutants covered by the final rule. The revised test methods have been published in a revised compendium (the "Pharmaceutical Methods Compendium, Revision A"; EPA-821-B-98-016, 1998) with the same title as the proposed compendium.

In addition EPA is allowing use of applicable drinking water methods that have been promulgated at 40 CFR Part 141 and use of ASTM Methods D3371, D3695, and D4763, for monitoring of the pollutants included in this rulemaking. The final rule allows for use of these additional test methods for several reasons: (1) it allows greater flexibility in monitoring, (2) it conforms use of methods in EPA's drinking water and wastewater programs, (3) it moves toward a performance-based measurement system, and (4) it allows use of technical standards as contemplated by the National Technology Transfer and Advancement Act of 1995 (NTTAA).

Table 17-1

Organic Pollutants Considered for Regulation That Pass Through POTWs

Pollutant	Passes Through Based on Volatilization Potential (a)	Passes Through Based on Water Soluble Compound Analysis	Passes Through Based on Evaluation of % POTW Removal
Acetone	X	X	X
Acetonitrile (b)			X
n-Amyl acetate	X	X	X
Amyl alcohol	X		X
Benzene	X	X	X
n-Butyl acetate	X	X	X
tert-Butyl alcohol	X		X
Chlorobenzene	X	X	X
Chloroform	X	X	X
o-Dichlorobenzene (1,2-Dichlorobenzene)	X	X	X
1,2-Dichloroethane	X	X	X
Diethylamine	X	X	X
N,N-Dimethylaniline	X		
Dimethyl sulfoxide (b)			X
Ethanol			X
Ethyl acetate	X	X	X
Formamide	X		X
n-Heptane	X	X	X
n-Hexane	X	X	X
Isobutyraldehyde	X	X	X
Isopropanol			X
Isopropyl acetate	X	X	X
Isopropyl ether	X	X	X
Methanol			X
Methyl cellosolve	X	X	NA
Methylene chloride	X	X	X
Methyl formate	X	X	X
Methyl isobutyl ketone (MIBK)	X	X	X

Table 17-1 (Continued)

Pollutant	Passes Through Based on Volatilization Potential (a)	Passes Through Based on Water Soluble Compound Analysis	Passes Through Based on Evaluation of % POTW Removal
Phenol (b)			
n-Propanol			X
Pyridine			X
Tetrahydrofuran	X	X	X
Toluene	X	X	X
Triethylamine	X	X	X
Xylenes	X	X	X

(a) Assumes a volatile override cutoff of Henry's Law Constant $\geq$ 1 x 10^{-5} atm/gmole/m^3.
(b) These pollutants are not treatable by the PSES/PSNS technology and are not regulated under PSES/PSNS in the final rule.
NA - No POTW % removal available.

Table 17-2

EPA and PhRMA Sampling Results for Primary Treatment at Barceloneta POTW Data from Method 1671

Pollutant	1996 Primary Treatment Data (Aerated Grit Chamber + Primary Clarifier)		1996 Primary Clarifier Only Data		1997 Primary Clarifier Only Data	
	Percent Loss	Percent Volatilization	Percent Loss	Percent Volatilization	Percent Loss(a)	Percent Volatilization (a)
Methanol	19.1	14.2-16.1	8.1	7.9-8.0	4.5-6.8	4.4-6.7
Ethanol	25.3	4.1-8.8	15.2	4.7-10.0	51.2-59.8	37.3-52.7
Isopropanol	11.4	0.0-5.1	5.9	0.0-5.5	10.8-18.2	8.3-13.4

(a) The ranges shown represent the average loss or volatilization amounts on Day 1 and 2, respectively.

Table 17-3

Water8 Modeling Results for Primary and Secondary Treatment at BRWTP

Pollutant	Percent Volatilization in Primary %	Percent Biodegradation in Primary %	Percent Volatilization in Secondary %	Percent Biodegradation in Secondary %	Percent Overall Volatilization %	Percent Overall Biodegradation %
Methanol	2.1	0.0	2.0	90.8	4.0	90.5
Ethanol	2.2	0.0	0.5	97.7	2.7	92.9
Isopropanol	4.2	0.0	10.8	74.0	14.3	77.0
Acetone	8.0	0.0	3.2	94.9	10.7	84.8
Chloroform	40.9	0.0	58.7	40.5	71.2	23.9
Methylene Chloride	38.9	0.0	70.4	28.6	78.2	17.8
Toluene	46.1	0.0	36.9	62.7	60.4	32.4

Note: Volatilization and biodegradation percentages may not add up to 100% since some of the compound remains in the effluent and some goes out with the sludge.

Table 17-4

Pollutants to be Regulated Under PSES and PSNS

Pollutant	Subcategories A and C	Subcategories B and D
Priority Pollutants		
Cyanide (a)	X	
Benzene	X	
Chlorobenzene	X	
Chloroform	X	
o-Dichlorobenzene (1,2-Dichlorobenzene)	X	
1,2-Dichloroethane	X	
Methylene Chloride	X	X
Toluene	X	
Non-Conventional Pollutants		
Acetone	X	X
Ammonia as N (b)	X	
n-Amyl Acetane	X	X
n-Butyl Acetate	X	
Diethylamine	X	
Ethyl Acetate	X	X
n-Heptane	X	
n-Hexane	X	
Isobutraldehyde	X	
Isopropyl Acetate	X	X
Isopropyl Ether	X	
Methyl Cellosolve Methyl Formate	X	
Methyl isobutyl ketone (MIBK)	X	
Tetrahydrofuran	X	
Thethylamine	X	
Xylenes	X	

(a) EPA is only clarifying the monitoring point on the existing regulation.
(b) Ammonia is only regulated for indirect dischargers that discharge to non-nitrifying POTWs.

Table 17-5

PSES and PSNS Effluent Limitations for Subcategory A and C Operations

Pollutant or Pollutant Property	PSES/PSNS for In-Plant Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Cyanide (1)	33.5	9.4

(1) Cyanide effluent limit established in the 1983 final rule, applies to Subcategory A and C operations only.

Pollutant or Pollutant Property	PSES Effluent Limitations End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Acetone	20.7	8.2
Ammonia as N (2)	84.1	29.4
n-Amyl Acetate	20.7	8.2
Benzene	3.0	0.6
n-Butyl Acetate	20.7	8.2
Chlorobenzene	3.0	0.7
Chloroform	0.1	0.03
o-Dichlorobenzene	20.7	8.2
1,2-Dichloroethane	20.7	8.2
Diethylamine	255.0	100.0
Ethyl Acetate	20.7	8.2
n-Heptane	3.0	0.7
n-Hexane	3.0	0.7
Isobutyraldehyde	20.7	8.2
Isopropyl Acetate	20.7	8.2
Isopropyl Ether	20.7	8.2
Methyl Cellosolve	275.0	59.7
Methylene Chloride	3.0	0.7
Methyl Formate	20.7	8.2
MIBK	20.7	8.2
Tetrahydrofuran	9.2	3.4
Toluene	0.3	0.1
Triethylamine	255.0	100.0
Xylenes	3.0	0.7

(2) Ammonia is only regulated for indirect dischargers that discharge to non-nitrifying POTWs.

Table 17-6

PSES and PSNS Effluent Limitations for Subcategory B and D Operations

Pollutant or Pollutant Property	PSES Effluent Limitations End-of-Pipe Monitoring Point	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Acetone	20.7	8.2
n-Amyl Acetate	20.7	8.2
Ethyl Acetate	20.7	8.2
Isopropyl Acetate	20.7	8.2
Methylene Chloride	3.0	0.7

Table 17-7

Steam Stripping Surrogates for Indirect Dischargers

Strippability Group	Compound	Surrogate (Yes/No)
High	Methylene Chloride	Yes
	Toluene	Yes
	Chloroform	Yes
	Methyl Cellosolve	No
	Xylenes	No
	n-Heptane	No
	n-Hexane	No
	Chlorobenzene	No
	Benzene	No
Medium	Acetone	Yes
	Ammonia as N	Yes
	Ethyl acetate	Yes
	Tetrahydrofuran	Yes
	Triethyamine	No
	MIBK	No
	Isopropyl acetate	No
	Diethylamine	No
	1,2-Dichloroethane	No
	n-Amyl acetate	No
	Isopropyl ether	No
	n-Butyl acetate	No
	Methyl formate	No
	Isobutraldehyde	No
	o-Dichlorobenzene	No

Yes-Surrogate pollutant for that strippability group.
No-Not a surrogate pollutant.

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4. USEPA, Effluent Guidelines Division, September 1982, "Fate of Priority Pollutants in Publicly Owned Treatment Works-Final Report."

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